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- (56) Documents Cited

  GB 2309903 A EP 0243248 A1 EP 0116439 A2

  EP 0019970 A1 WO 88/00822 A1 US 4855130 A
- (58) Field of Search
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- (54) Abstract Title

  A topical preparation for the promotion of hair growth or regrowth containing an absorption promoting agent and/or a blood thining agent
- (57) A topical formulation comprising an essential fatty acid, such as linolenic acid, an emollient, such as Evening Primrose oil, a citrus juice or oil, such as lemon or lime juice or oil, and either an absorption promoting agent, such as the vasodilators acetyl salicylic acid or glyceryl nitrate, or a blood-thinning agent, such as warfarin (RTM), or both, is used to promote hair growth and/or regrowth. The formulation may also be used as a cosmetic treatment to promote the fading of scar tissue, especially scar tissue resulting from burns. Ingredients of the formulation may fulfil more than one of those roles simultaneously, for example, acetyl salicylic acid (i.e., aspirin) will function as an absorption promoting agent and as a blood thinning agent because its action as a vasodilator will lead to increased absorption of the other ingredients of the preparation by the blood flowing to the scalp. Similarly, Evening Primrose oil which contains gamma-linolenic acid will serve as an emollient and provide an essential fatty acid. The formulation may also contain a vitamin component, preferably vitamin E. The composition (% by weight) of a preferred formulation is described. A variety of other ingredients such as surfactants and stabilizers may also be enclosed and the preparation may be in the form of a lotion, cream, emulsion, shampoo or a conditioner.

## TOPICAL PREPARATION

This invention relates to a topical preparation particularly, but not exclusively for promoting hair growth or regrowth, and to a method of treating hair loss, particularly from the scalp, using such a preparation. The topical preparation of the invention may also be used as a cosmetic treatment to promote the fading of scar tissue, particularly scars arising from burns.

Hair loss may arise due to stress in an individual, dietary deficiency, general alopecia or, particularly in male pattern baldness, due to heredity.

However, hair loss, particularly in women where it is less common, can cause anxiety, such anxiety may lead to further hair loss by causing stress which itself leads to hair loss.

Many formulations for promoting hair growth or regrowth are known, and may be applied topically or are orally or parenterally administered. Such formulations may modulate hormone activity or supplement dietary deficiencies thought to be responsible for hair growth, even when applied topically.

The presence of visible scars may cause an individual to feel unattractive and seek to remove or disguise the scar, scars usually being covered by cosmetic preparations to disguise them.

It is an object of the present invention to provide a topical preparation which promotes hair growth, that is strengthens and promotes growth of existing hair, and regrowth, that is stimulates hair follicles which have ceased to produce hair to recommence hair production. It

is a further object of the present invention to provide a method of treating baldness using such a preparation.

Accordingly, the present invention provides a topical preparation for the promotion of hair growth or regrowth, the preparation comprising an essential fatty acid, an emollient, a citrus juice or oil and an absorption promoting agent.

Preferably, the absorption promoting agent comprises acetyl salicylic acid (for example Aspirin, trade mark). The advantage of using acetyl salicylic acid is that it acts as both a blood-thinning or anti-thrombotic agent and as a vasodilator thereby increasing the absorption of the other ingredients by the blood flowing to the scalp. However, the use of blood-thinning agents which are not necessarily vasodilatory such as Warfarin (trade mark) is not to be excluded from the scope of the present invention. Similarly, the use of vasodilators such as glyceryl nitrate which do not have a blood thinning effect is not to be excluded from the scope of the present invention. Preferably, the absorption promoting agent is present in an amount of from 0.001 to 10%. Most preferably, 1.5%.

In a second aspect, the present invention provides a topical preparation for the promotion of hair growth or regrowth, the preparation comprising an essential fatty acid, an emollient, a citrus juice or oil and a blood-thinning or anti-thrombotic agent.

In a further aspect, the present invention provides a topical preparation for the promotion of hair growth or regrowth, the preparation comprising an essential fatty acid, an emollient, a citrus juice or oil and acetyl salicylic acid.

Preferably, the acetyl salicylic acid is present in an amount of from 0.001 to 10%. Most preferably 1.5%.

Preferably, the essential fatty acid is one which promotes hair growth or regrowth. Most preferably the essential fatty acid comprises gamma linolenic acid. Preferably, the essential fatty acid is present in an amount from 0.001% to 2%. More preferably 0.1 to 0.5%. The essential fatty acid may be dissolved in an appropriate vehicle.

Preferably, the emollient comprises an oil, preferably a vegetable oil, although mineral or synthetic oils are equally usable in the preparation. Conveniently the most preferred emollient comprises Evening Primrose oil. Evening Primrose oil comprises gamma linolenic acid and thus use of Evening Primrose oil in the topical preparation allows for the addition of two ingredients simultaneously. Preferably, the emollient is present in an amount of from 0.01% to 5%. More preferably, 1-3%. Mixtures of oils may be used to form the emollient.

Preferably, the citrus juice or oil is from lemons or limes. Preferably, the citrus juice or oil is present in an amount of from 10-30%, most preferably 12-17%.

Optionally, the preparation further comprises a vitamin.

More preferably, the preparation comprises a fat or oil soluble vitamin, for example vitamin E, vitamin A or vitamin D. The most preferred vitamin is vitamin E. Preferably, the topical preparation comprises less than 1% vitamin, most preferably 0.001-0.5% vitamin.

The preparation may be in the form of a lotion, cream, emulsion, shampoo, conditioner, gel or other cosmetically acceptable preparation.

Optionally, the preparation further comprises surfactants, cleansers, alcohols, excipients, stabilizers, anti-oxidants, vehicles or buffers.

The topical preparation of the invention may also be used in a cosmetic treatment to promote the fading of scar tissue, to prevent drying of the skin or to fade burn scars.

Embodiments of the invention will now be described by way of example only, with reference to the following examples:

**EXAMPLE 1**An emulsion for the promotion of hair growth or regrowth was prepared as follows:

	Weight (mg)	% by weight
Vitamin E	25	0.02
Gamma Linolenic Acid	200	0.16
Evening Primrose Oil	2275	1.8
Acetyl Salicylic Acid	4500	3.5
Lemon Juice	20000	15.75
Water	Balance to 100%	

The emulsion was freely applied to the scalp and massaged. After 15 minutes the unabsorbed emulsion was rinsed away with warm water and the hair and scalp dried. After two weeks, new hair growth was detectable by eye, and new growth of existing hair appeared stronger.

## **EXAMPLE 2**

The emulsion of Example 1 was added to a base shampoo formulation, instead of water. The shampoo formulation was used in place of ordinary shampoo. After two weeks, hair regrowth was detectable.

## **EXAMPLE 3**

The emulsion of formula 1 was incorporated into an aqueous base cream and liberally applied on a daily basis to scar tissue resulting from a burn. After two weeks, fading of the scar tissue was visible by eye.

## **CLAIMS:**

- A topical preparation for the promotion of hair growth or regrowth, the preparation comprising an essential fatty acid, an emollient, a citrus juice or oil and an absorption promoting agent and/or a blood-thinning or anti-thrombotic agent.
- 2. A preparation according to claim 1, in which the absorption promoting agent comprises acetyl salicylic acid.
- 3. A preparation according to claim 1, in which the absorption promoting agent comprises glyceryl nitrate.
- 4. A preparation according to claim 1, in which the absorption promoting agent comprises Warfarin (trade mark).
- 5. A preparation according to any preceding claim, in which the absorption promoting or blood-thinning or anti-thrombotic agent is present in an amount of from 0.001% to 10%.
- 6. A preparation according to any one of claims 1 to 4, in which the absorption promoting or blood-thinning or anti-thrombotic agent is present in an amount of 1.5%.
- 7. A preparation according to claim 1, in which the blood-thinning or anti-thrombotic agent comprises acetyl salicylic acid.

- 8. A topical preparation for the promotion of hair growth or regrowth, the preparation comprising an essential fatty acid, an emollient, a citrus juice or oil and acetyl salicylic acid.
- A preparation according to any of claims 2 or 5 to 8, in which acetyl salicylic acid is present in an amount of from 0.001% to 10%.
- 10. A preparation according to any one of claims 2 or 5 to, in which acetyl salicylic acid is present in an amount of 1.5%.
- 11. A preparation according to any preceding claim, in which the essential fatty acid is present in an amount of from 0.001% to 2%.
- 12. A preparation according to any one of claims 1 to 10, in which the essential fatty acid is present in an amount of 0.1% to 0.5%.
- 13. A preparation according to any preceding claim, in which the essential fatty acid is dissolved in a vehicle.
- 14. A preparation according to any preceding claim, in which the essential fatty acid comprises gamma linolenic acid.
- 15. A preparation according to any preceding claim, in which the emollient comprises an oil.

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- 16. A preparation according to claim 15, in which the oil is selected from the group consisting of vegetable oils, mineral oils, synthetic oils or mixtures thereof.
- 17. A preparation according to claim 15, in which the oil comprises Evening Primrose oil.
- 18. A preparation according to any preceding claim, in which the emollient is present in an amount of from 0.01% to 5%.
- 19. A preparation according to any one of claims 1 to 17, in which the emollient is present in an amount of from 1% to 3%.
- 20. A preparation according to any preceding claim, in which the citrus juice or oil is lemon or lime juice or oil.
- 21. A preparation according to any preceding claim, in which the citrus juice or oil is present in the amount of from 10% to 30%.
- 22. A preparation according to any one of claims 1 to 20, in which the citrus juice or oil is present in an amount of from 12% to 17%.
- 23. A preparation according to any preceding claim further comprising a vitamin.
- 24. A preparation according to claim 23, in which the vitamin is a fat- or oil- soluble vitamin.

- 25. A preparation according to claim 23 or 24, in which the vitamin is selected from vitamin E, vitamin A, vitamin D, or mixtures thereof.
- 26. A preparation according to any one of claims 23 to 25, in which the preparation comprises less than 1% vitamin.
- 27. A preparation according to any one of claims 23 to 25, in which the preparation comprises 0.001% to 0.5% vitamin.
- 28. A preparation according to any preceding claim, further comprising surfactants, cleansers, alcohols, excipients, stabilisers, antioxidants, vehicles, buffers, or mixtures thereof.
- 29. Use of a preparation according to any preceding claim, in a lotion, cream, emulsion, shampoo, conditioner, gel or other cosmetically acceptable preparation for use in the treatment of baldness.

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- 30. Use of a preparation according to any preceding claim in a cosmetic treatment for baldness.
- 31. Use of a topical preparation according to any preceding claim in a cosmetic treatment to promote the fading of scar tissue.
- 32. A topical preparation for use in a cosmetic treatment for baldness substantially as hereinbefore described.

33. A topical preparation for use in a cosmetic treatment to promote the fading of scar tissue, substantially as hereinbefore described.





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Claims searched: 1-33

Examiner: Date of search:

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Patents Act 1977
Search Report under Section 17

## Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.P): A5B (BFC)

Int Cl (Ed.6): A61K 7/06

Other: Online: EPODOC

## Documents considered to be relevant:

Category	Identity of documer	nt and relevant passage	Relevant to claims
X, Y	GB 2309903 A	(BUCK) see page 5, lines 60-11; see formula composition, page 11; see page 14, lines 3-5.	X, Y: 1, 5, 15, 16, 18, 19, 28- 30
X, Y	EP 0243248 A1	(ROCHE-POSAY) see abstract, see Example 8, see col 2, line 44 to col 3, line 23; col 4, lines 6-11 and lines 44-46.	X, Y: 1, 5, 15, 16, 18, 19, 23- 30
Y	EP 0116439 A2	(SUNTORY) see examples 1-71, page 2, line 10 to page 3, line 10	1, 5, 15, 16, 18, 19, 23-30
Y	EP 0019970 A1	(PROCTOR & GAMBLE) see examples 1 & 2, lines 10-17, page 5.	1, 5, 15, 16, 18, 19, 28-30
X, Y	WO 88/00822 A1	(UPJOHN) see Formula 1; page 4, line 21 to page 7, line 5 and especially page 5, lines 21-26	X, Y: 1, 5, 6, 28-30
Y	US 4855130 A	(KONRAD et al.) see examples 1 and 2	1, 5, 28, 29

- X Document indicating lack of novelty or inventive step
   Y Document indicating lack of inventive step if combined
- with one or more other documents of same category.
- A Document indicating technological background and/or state of the art.
- P Document published on or after the declared priority date but before the filing date of this invention.
- & Member of the same patent family
- E Patent document published on or after, but with priority date earlier than, the filing date of this application.





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Category	Identity of document and relevant passage	Relevant to claims

Document indicating lack of novelty or inventive step

Document indicating lack of inventive step if combined
with one or more other documents of same category.

<sup>&</sup>amp; Member of the same patent family

A Document indicating technological background and/or state of the art.

P Document published on or after the declared priority date but before the filing date of this invention.

E Patent document published on or after, but with priority date earlier than, the filing date of this application.